UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EVERETT LABORATORIES, INC., Plaintiff, v. ACELLA PHARMACEUTICALS, LLC, Defendant.

HONORABLE JOSEPH E. IRENAS

CIVIL ACTION NOS. 13-3470, 13-3487, 13-3529 (JEI/KMW)

OPINION

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Irenas, Senior District Judge:

This is a patent infringement case. Plaintiff Everett Laboratories, Inc. ("Everett") has filed several actions against Defendant Acella Pharmaceuticals, LLC ("Acella") alleging that Acella has infringed Everett's patents for a variety of nutritional supplements. Presently before the Court are three Motions for Preliminary Injunction by Everett. For the reasons discussed below, these Motions will be denied.[1]

I.

Plaintiff Everett is a company that develops, markets, and sells prescription-only branded nutritional supplements. Defendant Acella sells lower cost versions of similar supplements. The three instant suits involve three prenatal supplements that Everett sells. Those supplements are Vitafol-

[1] This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a)-(b).

OB+DHA, Select-OB+DHA, and Vitafol-One.[2] All three products have different compositions of vitamins and minerals as well as different delivery forms. For example, Vitafol-OB+DHA is a caplet; Select-OB+DHA is a two-component kit consisting of a chewable caplet containing vitamins and minerals as well as a soft gel capsule containing docosahexaenoic acid ("DHA") and lauric acid; and Vitafol-One is a soft gel capsule containing vitamins, minerals, and DHA.

Everett has spent considerable amounts of money researching, developing, manufacturing, and promoting its products. A significant portion of its marketing strategy involves in-person, one-on-one visits with doctors. These strategies have been effective, as each of the supplements has shown a high degree of commercial success, generating tens of millions of dollars in sales for Everett since the first supplement, Vitafol-OB+DHA, was introduced in February 2007.

Sales of prescription-only nutraceuticals take place through a multitiered system. Manufacturers, such as Everett, sell their products to wholesalers who then sell the products to retail pharmacies.[3] The wholesalers select the amount of product

[2] Everett has filed a fourth suit against Acella alleging patent infringement of an unrelated nutritional supplement, Strovite One, which is a multivitamin. *See Everett Labs., Inc. v. Acella Pharm., LLC*, 13-cv-4294 (JEI/KMW).

[3] Some of the larger pharmacy chains, such as Rite-Aid or Walgreens, are large enough that manufacturers make direct sales to them.

to buy in anticipation of what their expected future sales will be. Approximately 93% of Everett's sales are to wholesalers.

Commercial drug databases are another aspect of the pharmaceutical and nutraceutical industry. These databases provide information to wholesalers, pharmacies, pharmacists, and third-party payers about pricing and generic versions of branded products, which in turn help the pharmacies decide whether to dispense a branded product or its generic equivalent. For products to be linked in these databases, their key ingredients must be identical in type, content, and amount. After this linkage occurs, a pharmacist filling a prescription for a brand-name product will see all of the available substitutable products for that branded product on her computer system. The pharmacist may then substitute a lower-cost generic version of the product. States have varying laws on whether a patient must consent to or be notified of a substitution before it occurs.

Starting in June 2013, Acella began selling lower-cost versions of Everett's supplements. Acella's allegedly infringing products are PNV-OB with DHA, Choice-OB+DHA, and PNV-First. These products correspond to Vitafol-OB+DHA, Select-OB+DHA, and Vitafol-One, respectively. Acella's supplements are linked to Everett's supplements in various drug databases.

Everett filed these three actions in early June 2013. Everett claims that Acella has infringed its patents for

Vitafol-OB+DHA, Select-OB+DHA, and Vitafol-One. There are four patents-in-suit: U.S. Patent Nos. 6,814,983 ("the '983 patent"), 7,390,509 ("the '509 patent"), 8,197,855 ("the '855 patent"), and 8,183,227 ("the '227 patent"). The '983 and the '509 patents cover Vitafol-OB+DHA; the '855 patent covers Select-OB+DHA; and the claims in the '227 patent cover Vitafol-One. In late June and early July 2013, Everett filed the instant Motions for Preliminary Injunction. The Court held a three-day hearing on these motions on August 19-21, 2013.

II.

A preliminary injunction is a drastic remedy that is not routinely granted. *Nat'l Steel Car, Ltd. v. Canadian Pacific Ry., Ltd.*, 357 F.3d 1319, 1324 (Fed. Cir. 2004). In deciding whether to grant a preliminary injunction, a court must consider four factors: 1) whether there is a reasonable likelihood of success on the merits; 2) the likelihood of irreparable harm if the injunction is not granted; 3) whether the balance of hardships tips in the moving party's favor; and 4) whether an injunction is in the public interest. *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 695 F.3d 1370, 1373-74 (Fed. Cir. 2013) (citing *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). "[A] movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors,

i.e., likelihood of success on the merits and irreparable harm." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) (emphasis in original).

III.

A. Likelihood of Success on the Merits

"To demonstrate a likelihood of success on the merits, a patentee must show that, in light of the presumptions and burdens that will inhere at trial on the merits: (1) the patentee will likely prove that the accused infringer infringes the asserted patent; and, (2) the patentee's infringement claim will likely withstand the accused infringer's challenges to the validity and enforceability of the patent." *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1259 (Fed. Cir. 2012). If the nonmoving party raises an infringement or validity defense that the moving party cannot show lacks substantial merit, the preliminary injunction should not be granted. *Amazon.com*, 239 F.3d at 1351. "A patent holder seeking a preliminary injunction bears the ultimate burden of establishing a likelihood of success on the merits with respect to the patent's validity." *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009). The accused infringer has a lower burden for showing a substantial question of invalidity at the preliminary injunction stage than it does at trial. *Id.* at 1006.

"Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial." *Amazon.com*, 239 F.3d at 1359.

Everett claims that it has a high likelihood of success on the merits because Acella's products clearly infringe Everett's patents and those patents are valid. Acella counters that the patents-in-suit are invalid because they are obvious under 35 U.S.C. § 103 in light of the prior art.[4] Acella also argues that the '855 patent is invalid as anticipated under 35 U.S.C. § 102.

A patent may not issue "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. Whether a patent is obvious is a question of law grounded in underlying factual determinations. *Altana*, 566 F.3d at 1007. The relevant factual determinations are "(1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) evidence of secondary factors, known as objective indicia of nonobviousness." *Id.* (citing *Graham v. John Deere Co.*, 383 U.S.

[4] Because Acella does not dispute infringement for the purposes of these Motions, the only question before the Court is whether the patents can withstand Acella's challenges to validity.

1, 17-18 (1966)). When making an obviousness determination, the Court should consider whether a person having ordinary skill in the art would have had reason to attempt to make the composition and would have had a reasonable expectation of success. *Pharmastem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

At this point in the case, the Court finds that Acella has raised a substantial question of invalidity that Everett has not shown lacks substantial merit.[5] Because the analysis is different for each patent, the Court addresses them separately.

1. The ’983 and ’509 Patents

These patents cover the composition of Everett’s Vitafol-OB+DHA product. Acella argues that the patents are invalid because Published International Patent Application WO97/48392 (“the ’392 Publication”), which was published in 1997, discloses a supplement that includes all of the compounds in the patents. It contends that the publication also discloses corresponding amounts for each compound, with the exception of magnesium.

After reviewing the ’392 Publication, the Court agrees that Acella has shown a substantial question of obviousness. The ’392 Publication discloses every component claimed in the ’983 and ’502 patents. Further, the ’392 Publication provides both

[5] The Court emphasizes that this finding is preliminary and that Acella’s arguments might not withstand a full trial on the merits.

ranges and specific amounts of each component that correspond with the amounts claimed in the patents. In some cases, the amount specified in the ’392 Publication is identical to the amount claimed in the ’983 and ’502 patents.

The ranges listed for the other components also support finding that that the patents may be obvious, as the amounts claimed in the patents all fall within the ranges in the ’392 Publication. The Federal Circuit has made clear that “[s]electing a narrow range from *within* a somewhat broader range disclosed in a prior art reference” is presumed obvious. *In re Peterson*, 315 F.3d 1325, 1329-30 (Fed. Cir. 2003). The presumption of obviousness is particularly pertinent here where the disclosed ranges are fairly narrow. *See, e.g.*, *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 402-03 (2007) (“When . . . there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.”). As such, it would be no great innovation for a person of ordinary skill in the art to select the amounts claimed in the ’983 and ’502 patents.

Everett’s argument that the ’392 Publication teaches away from the ’983 and ’502 patents because it includes iodine and suggests the inclusion of magnesium rather than requiring it is insufficient to overcome Acella’s showing at this stage. First,

the Court finds that the inclusion of iodine in the ’392 Publication’s claims is not dispositive. The publication also indicates that “[i]odine *can* be present,” thereby suggesting that iodine is not a necessary part of the supplement. (’392 Publication, 11 l.5) Thus, a person having ordinary skill in the art could be motivated to exclude iodine.

Second, with respect to magnesium, Acella’s expert, Dr. Robert Newman, testified that magnesium is commonly included in prenatal supplements in the amount (25 mg) disclosed in the patents at issue here and that one skilled in the art would be motivated to include magnesium in that amount in a supplement. (Newman Decl. ¶ 92) Although Acella may be required to provide more evidence supporting this assertion at trial, Dr. Newman’s testimony is sufficient at the preliminary injunction stage. Accordingly, the Court finds that Acella has raised substantial questions as to the validity of the ’983 and ’509 patents.

2. The ’227 Patent

The ’227 patent is directed to the supplement that Everett sells as Vitafol-One. Acella argues that claim 1 of the ’227 patent is obvious because the *Monthly Prescribing Reference* (“MPR”) disclosed each vitamin and mineral claimed in the patent. Acella further argues that the components and amounts required in the ’227 patent were disclosed in a scholarly

article ("Bentley article").[6] The Court agrees that theses references raise a substantial question of obviousness.

Much like the '392 Publication, the MPR and the Bentley article provide lists of each vitamin and mineral found in claim 1 of the '227 patent and then specify ranges that encompass the amounts specified in the '227 patent, with the exception of Vitamin D. As noted above, when a patent claims an amount that is within a previously disclosed range, it raises a presumption of obviousness. With respect to Vitamin D, Acella has put forth evidence that relevant literature at the time suggested increasing the amount of Vitamin D in supplements. (*See, e.g.*, Newman Decl. ¶ 43)

Everett's argument that these references teach away from including some of the vitamins and minerals in the '227 patent is unavailing. The vitamins and minerals listed in the '227 patent were all included in the MPR and the Bentley article, and as became apparent during oral argument, a person having ordinary skill in the art could have been motivated to include those vitamins and minerals in similar amounts based on the recommended daily doses at the time. As such, the Court finds that Acella has shown that the '227 patent is vulnerable at this stage in the case.

[6] Acella also argues that the '983 patent renders the '227 patent obvious. However, as the Court finds that the MPR and the Bentley article raise a substantial question of invalidity, the Court does not reach this question.

3. The ’855 Patent

The ’855 patent discloses claims for the supplement Select-OB+DHA. Acella argues that this patent is invalid because it was anticipated by International Patent Application WO 03/092674 (“the ’674 Publication”), International Patent Application WO 01/12163 (“the ’163 Publication”), and U.S. Patent No. 6,495,177 (“the ’177 patent”). It also argues that the ’227 patent is invalid because it is obvious in light of the combined teachings of the ’163 Publication and the ’177 patent.

Anticipation is a question of fact. *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). “For a prior art reference to anticipate a claim, the reference must disclose each claim limitation in a single document.” *Apple Inc. v. Int’l Trade Comm’n*, 2013 WL 4007535, at *4 (Fed. Cir. 2013) (not yet published); *see also Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1381 (Fed. Cir. 2006) (“A patent claim is invalid as anticipated if every limitation in a claim is found in a single prior art reference, either explicitly or inherently.”). A product that would literally infringe if it came after the asserted patent anticipates if it comes before the asserted patent. *Upsher-Smith Labs., Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1322 (Fed. Cir. 2005).

Based on the record before it, the Court finds that Acella has raised a substantial question of anticipation. The ’674 Publication, the ’163 Publication, and the ’177 patent correspond to the asserted claims of the ’855 patent. First, both the ’674 Publication and the ’177 patent disclose each element of claim 1 of the ’855 patent. Second, the ’674 Publication discloses the vitamins and minerals claimed in claims 6-13 and 15-18 of the ’855 patent, and the ’177 patent describes the vitamins and minerals in claims 4-12 and 15-18 of the ’855 patent. The ’163 Publication addresses the compositions claimed in claims 4-5 of the ’855 patent. Third, both the ’674 Publication and the ’177 patent address the administration claims in the ’855 patent by describing methods of administering the compounds to patients.

Everett fails to demonstrate that Acella’s showing of vulnerability lacks substantial merit. First, the fact that the ’674 Publication discloses additional optional minerals that are not included in claim 1 of the ’855 patent is not dispositive at this stage. *See Upsher-Smith Labs.*, 412 F.3d at 1322 (holding that prior art that allowed for the “optional inclusion” of antioxidants in a vitamin supplement anticipated compositions that both included and did not include antioxidants). The fact that the ’674 Publication contains a reason to include calcium where the ’855 patent excludes it does not defeat anticipation

either. *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001) ("[A] reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. Thus, the question whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis."). Similarly, the fact that the '177 patent does not include magnesium and zinc in a specific embodiment but suggests that it may be included later in the specifications is enough to raise a substantial question that the '177 patent anticipated the '855 patent.

Second, Everett argues that the '674 Publication does not disclose a supplement that is both chewable and swallowable. However, at oral argument it became apparent that there is much dispute as to whether a supplement designed to be chewed could be swallowed and have the same or similar therapeutic effect. At this point, the Court cannot say that Everett has shown that a supplement that is both chewable and swallowable is so different from a chewable tablet as to defeat anticipation.

Third, the fact that the '177 patent discloses the inclusion of *either* beta carotene or Vitamin A rather than *both* beta carotene and Vitamin A as claimed in the '855 patent is unpersuasive. Once again, the Court heard differing testimony at oral argument regarding whether a person having ordinary skill in the art would consider beta carotene and Vitamin A to

be interchangeable and whether such a person would consider including both in a nutritional supplement. Faced with such divergent opinions, the Court concludes that this difference does not discredit Acella's anticipation argument.

Fourth, the difference between the '177 patent's requirement of an oligosaccharide derivative of iron as opposed to the '855 patent's requirement of a polysaccharide iron complex is not dispositive at this time. The testimony at oral argument indicates that while polysaccharides and oligosaccharides can be different structures, they may also overlap.[7]

For all of these reasons, the Court finds that Acella has raised a substantial question of invalidity with regard to the '855 patent such that a preliminary injunction should not issue.

B. Irreparable Harm

Although the preliminary injunction analysis may end with the Court's finding that Acella has raised a substantial question of invalidity, *see Amazon.com*, 239 F.3d at 1350 ("Our case law and logic both require that a movant cannot be granted

[7] Even if the '674 Publication, the '163 Publication, and the '177 patent did not anticipate the '855 patent, the '177 patent and the '163 Publication render the '855 patent obvious. Taken together, these references would lead a person having ordinary skill in the art to the compositions claimed in the '855 patent. As noted above, the references disclose each element of the '855 patent, including both composition and method claims, and suggest that the tablet may be swallowable and chewable. A person having ordinary skill in the art could be motivated to combine these references to create the composition claimed in the '855 patent.

a preliminary injunction unless it establishes *both* of the first two factors . . . ."), in light of Everett's emphasis on irreparable harm, the Court also addresses that element. Everett contends that it will suffer loss of market share and loss of goodwill. Everett also argues that it faces a "Hobson's choice": it must either stop marketing its products and risk loss of sales to both Acella and other nutritional supplement companies, or it will continue to market its products only to see sales go to the generic, Acella.

When examining irreparable harm, the court must determine whether there will be injury that no damages award could remedy. *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012). "It is well established that . . . the party seeking emergency relief . . . 'must make a clear showing that it is at risk of irreparable harm, which entails showing a likelihood of substantial and immediate irreparable injury.'" *Apple Inc.*, 695 F.3d at 1374 (quoting *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012)). Although loss of market share and sales, loss of goodwill, and price erosion may support a finding of irreparable harm, these types of harms do not automatically support such a finding. *Altana Pharma*, 566 F.3d at 1010-11.

On the record before it, the Court cannot find that Everett will suffer irreparable harm. While neither party has presented

convincing data on this subject, the burden is on Everett to show that any harm it will suffer cannot be remedied by damages at a later date. It has not done so.[8]

First, Everett claims that it will lose more than 90% of its market share within a year as a result of Acella's linking. To bolster this contention, it offers the declaration of its Chief Executive Officer, Lucas Sigman, and two experts, Bruce Brown and Brian Reisetter. But none of these declarations provides convincing support for this figure. Mr. Brown and Mr. Reisetter both summarily state that, based on their individual experiences in the industry, Everett will lose 90% of its market share within a year.[9] (Brown Decl. ¶ 26; Reisetter Decl. ¶ 19)

Mr. Sigman relies on Acella's history with another branded company, Sciele Pharma, Inc., to support his contention that Everett will lose more than 90% of its market share. (Sigman Decl. ¶¶ 68-71) According to Mr. Sigman, once Acella linked its products with Sciele's products, it was able to acquire from 60% to more than 90% of the market share for those products in a relatively short period of time. (*Id.* ¶¶ 68-70) But while the

[8] In reaching this conclusion, the Court does not suggest that loss of market share, sales, and good will as well as price erosion cannot form the basis for a finding of irreparable harm. Rather, the Court finds that Everett has not presented sufficient evidence to demonstrate that it likely will suffer these harms.

[9] The Court also notes that Everett appears to be using lost sales and lost market share interchangeably.

Sciele example[10] is informative, it does not demonstrate that the exact same thing will happen to Everett. Sciele's products were not patented, and there is no indication that Sciele employed marketing strategies similar to Everett's.

Mr. Sigman also references Everett's experience when Trigen Laboratories linked two of its products to Everett's Vitafol-One and Select-OB+DHA products. According to Mr. Sigman, Trigen diverted 30% and 24% of Everett's sales in those products, respectively, within three months. (*Id.* ¶ 75) Again, the Court is reluctant to rely on the Trigen example to extrapolate what may happen in this case in the absence of any other data and without knowing how analogous the situations actually are. Further, the Court notes that there is some evidence provided by Acella's expert, Bryce Cook, that Everett's sales recovered fairly quickly after it reached a settlement with Trigen to halt Trigen's sales of its allegedly infringing products.[11] (Hearing D-10, Chart 8)

As for loss of goodwill, Everett argues that patients and doctors will attribute any adverse experiences with Acella's products to Everett because they will not know that Acella's product has been substituted for Everett's. Both parties have

[10] The parties also refer to Sciele by the name of its parent company, Shionogi.

[11] The Court is aware that this data is somewhat misleading, as it reflects Everett's total sales for all of its products, not just the products that Trigen targeted. However, it does cast doubt on Everett's claim that any market share lost could not be regained.

provided conflicting accounts of what state laws require with respect to patient consent before substituting a generic for a branded prescription. But regardless of whether most states require patient consent as Acella argues, or whether most states provide only for some kind of notification as Everett contends, the Court does not find this information to be particularly helpful. State laws regarding the substitution of generic *pharmaceuticals* for branded pharmaceuticals do not necessarily equate to how a state treats *nutraceuticals*, which are at issue in this case.

With respect to Everett's Hobson's choice argument, the Court sympathizes with the situation Everett faces. But the fact remains that Everett has not shown that it will suffer irreparable harm because of this choice. At oral argument, counsel for Everett represented that in the weeks since Acella entered the market, Everett has continued to pursue its product marketing strategy pending the resolution of these Motions. Neither party has provided sufficient data with respect to Everett's loss of sales or market share during this period. The Court recognizes that the distribution system is such that substitution of Acella's products for Everett's may be slow. However, the Court cannot justify granting the extraordinary relief of a preliminary injunction given the paucity of data currently available. While the very nature of a preliminary

injunction suggests that there will be some speculation as to irreparable harm, more tangible evidence is required than the mere conjecture offered here. As such, the Court finds that Everett has not met its burden on irreparable harm and thus is not entitled to a preliminary injunction.[12]

IV.

For the reasons given above, Everett's Motions for Preliminary Injunction will be denied. An appropriate Order accompanies this Opinion.

Date: August 29, 2013

/s/ Joseph E. Irenas

Joseph E. Irenas, S.U.S.D.J.

[12] Because Everett has failed to establish the first two prongs of the preliminary injunction inquiry, the Court declines to consider the balance of hardships and the public interest.